4. 510(k) Summary according to 807.92

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Reverse Medical Corporation is providing the summary of Substantial Equivalence for the ReFlex™ Balloon Guide Catheter.

4.1 Sponsor /Applicant Name and Address

Reverse Medical Corporation
13900 Alton Parkway
Suite 123
Irvine, CA 92618

4.2 Sponsor Contact Information

Jeff Valko, President & CEO
Phone: 949-215-0660 x201
Fax: 949-215-0661
Email: jvalko@reversemed.com

4.3 Date of Preparation of 510(k) Summary

August 5, 2011

4.4 Device Trade or Proprietary Name

ReFlex™ Balloon Guide Catheter

4.5 Device Common/Usual or Classification Name

Catheter, Percutaneous (Product Code: DQY)

4.6 Identification of the Legally Marketed Devices to which Equivalence is Being Claimed:

Name of Predicate Devices	Name of Manufacturer (Town, State)	510(k) Number
Concentric Balloon Guide Catheter	Concentric Medical, Inc. Mountain View, CA	K010954 K021899

510(k) Summary according to 807.92 (continued)

4.7 Device Description

The ReFlex™ Balloon Guide Catheter is a flexible, variable stiffness composite catheter. The catheter shaft has a hydrophilic coating to reduce friction during use. A compliant balloon is mounted on the distal end of the catheter. The ReFlex™ Balloon Guide Catheter dimensions are included on the individual device labels. The ReFlex™ Balloon Guide Catheter inner lumen can accommodate guidewires up to 0.038 inches in diameter to aid in placement of the catheter system.

The proximal end of the ReFlex™ Balloon Guide Catheter has a bifurcated luer fitting to allow attachment of accessories and infusion of liquids through the system. The ReFlex™ Balloon Guide Catheter is offered in various sizes to accommodate physician preferences and anatomical variations. The catheter is provided sterile, non-pyrogenic, and is intended for single use only.

4.8 Intended Use

The Reverse Medical ReFlex™ Balloon Guide Catheter is indicated for use in facilitating and guidance of intravascular catheters into selected blood vessels in the peripheral and neurovascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.

4.9 Comparison to Predicate Devices

	Concentric Balloon Guide Catheter	ReFlex™ Balloon Guide Catheter
510(k) Numbers	K010954, K021899	TBD
Classification	Class II, DQY	Class II, DQY
Indication	Indicated for use in facilitating and guidance of intravascular catheters into a selected blood vessel in the peripheral and neurovascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.	Indicated for use in facilitating and guidance of intravascular catheters into a selected blood vessel in the peripheral and neurovascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.
Shaft Materials	Coaxial lumen braided shaft variable stiffness catheter with radiopaque marker on distal end.	Dual lumen wire reinforced shaft variable stiffness catheter with radiopaque marker on distal end.
Proximal End Configuration	Luer Hub	Luer Hub
Radiographic markers/radiopacity	Radiopaque marker at distal tip	Radiopaque marker at distal tip
Balloon	Compliant	Compliant
Packaging	Catheter attached to packaging card inside PET/PE/Tyvek pouch inside SBS carton.	Catheter in polyethylene hoop attached to packaging card inside PET/PE/Tyvek pouch inside SBS carton.
Sterilization	EtO	EtO

510(k) Summary according to 807.92 (continued)

4.10 Summary of Non-Clinical Data

4.10.1 Biocompatibility and Sterilization

The ReFlex™ Balloon Guide Catheter is classified as Externally Communicating Devices, Circulating Blood, Limited Contact (≤ 24 hours). Results of the testing demonstrate that the blood contacting materials are biocompatible.

Blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993-1 guidelines "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." The ReFlex™ Balloon Guide Catheter successfully passed all of the following biocompatibility tests:

Test	Method
Cytotoxicity	L929 MEM Elution Test
Sensitization	Kligman Maximization
Intracutaneous Reactivity (Irritation)	Intracutaneous Injection Test
Systemic Toxicity (Acute)	ISO Acute Systemic Injection Test
Hemocompatibility	Complement Activation
	Hemolysis
	Inactivated Partial Thromboplastin Time Test
	In vivo thrombogenicity
Pyrogenicity	USP Material Mediated Rabbit Pyrogen Test
EtO Residuals	Ethylene oxide and Ethylene chlorohydrins residuals

Sterilization conditions have been validated according to ANSI / AAMI / ISO 11135, *Sterilization of Health Care Products-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* to provide a Sterility Assurance Level (SAL) of 10^{-6}.

4.10.2 Design Verification (Bench-Top Testing)

The physical, mechanical, and performance testing of the ReFlex™ Balloon Guide Catheter demonstrate that the product is substantially equivalent to the currently marketed predicate devices. Design verification testing was conducted to evaluate the physical and mechanical properties of the ReFlex™ Balloon Guide Catheter. All studies were conducted in accordance with Reverse Medical Design Control procedures. All testing was performed on units that were sterilized and met all inspection criteria. Tests on the ReFlex™ Balloon Guide Catheter included:

Verification and Test Summary

***In vitro* Tests**	**Result**
Dimensional and Visual Inspection	Met established criteria
Guidewire Compatibility	Met established criteria
Microcatheter Compatibility	Met established criteria
Torque Strength	Met established criteria
Kink Resistance	Met established criteria
Tip Buckling Test	Met established criteria
Flexibility Test (including tip flexibility)	Met established criteria
Tensile Strength	Met established criteria
Catheter Leak Test (Liquid Leakage)	Met established criteria
Catheter Leak Test (Air Leakage)	Met established criteria
Dynamic Pressure Test	Met established criteria
Static Burst Test	Met established criteria
Aspiration Test	Met established criteria
Hub Gauging	Met established criteria
Corrosion Resistance	Met established criteria
USP Particulate Test	Met established criteria
Navigation, Accessibility, & Simulated Vascular Occlusion Capabilities *in vitro*	Met established criteria
Balloon Inflation/Deflation Times	Met established criteria
Balloon Cycle Fatigue	Met established criteria
Balloon Rated Volume (informational purposes)	Met established criteria
Balloon Compliance (informational purposes)	Met established criteria
***In vivo* Tests**	**Result**
System Deliverability, Compatibility, Visibility, and Temporary Vascular Occlusion Performance	Met established criteria
Acute Histopathology of Treated Vessels	Met established criteria
Biocompatibility Testing	Met established criteria

The physical, mechanical, and performance testing of the subject ReFlex™ Balloon Guide Catheter demonstrate that the product is Substantially Equivalent to the currently marketed predicate devices.

4.11 Substantial Equivalence

The performance of the ReFlex™ Balloon Guide Catheter in this submission demonstrates that the product is substantially equivalent to the performance of the predicate devices. The equivalence was shown through comparison of component materials and specifications, performance, biocompatibility testing, and sterilization validation.

The ReFlex™ Balloon Guide Catheter is substantially equivalent in intended use, design, technology/principles of operation, materials, and performance to the predicate devices. Differences between the devices do not raise any significant issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV - 2 2011

Reverse Medical Corporation
c/o Mr. Jeffrey Valko
13700 Alton Parkway Suite 167
Irvine, CA 92618

Re: K112262
Trade Name: ReFlex Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: October 10, 2011
Received: October 11, 2011

Dear Mr. Valko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

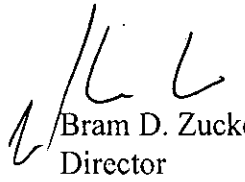
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indications for Use

510(k) Number (if known): K112262

Device Name: Reverse Medical ReFlex™ Balloon Guide Catheter

Indications for Use:

The Reverse Medical ReFlex™ Balloon Guide Catheter is indicated for use in facilitating and guidance of intravascular catheters into a selected blood vessel in the peripheral and neurovascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over the Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ICL

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112262